

## Remarks

### **The Office Action Summary**

The Office Action Summary notes in item number 8 that claims 1-33 are subject to a restriction and/or election requirement. However, no such requirement has been made. Applicants respectfully request clarification.

### **The Amendments**

Claim 1 has been amended to recite a housing. Support for the amendment can be found in the specification at, *inter alia*, page 17, lines 20-23. Claim 1 has also been amended to clarify that the sample collector is associated with the sampler member. Support for the amendment can be found in the specification at, *inter alia*, page 12, lines 9-15 and Figure 2.

Claim 6 has been amended to clarify the sample collector is located in the sampler member. Support for the amendment can be found in the specification at, *inter alia*, page 12, lines 9-15 and Figure 2. This amendment is not a narrowing amendment, the amendment merely clarifies the claim.

Claim 10 has been amended to clarify that the end of the sample collector recited in the claim is the end that is in contact with the reagent delivery system. Support for the amendment can be found in the specification at, *inter alia*, page 16, lines 17 through page 17, line 19 and Figure 4. This is not a narrowing amendment, the amendment merely clarifies the claim.

Claim 12 has been amended to clarify that the sampler member comprises a sharp. Support for the amendment can be found in the specification at, *inter alia*, page 15 lines

3-12 and Figures 6 and 7. This is not a narrowing amendment, the amendment merely clarifies the claim.

Claim 15 has been amended to clarify that the end of the transit zone recited in the claim is the end that is opposite of the capture zone. Support for the amendment can be found in the specification at, *inter alia*, page 13, lines 6-9 and Figure 2. This is not a narrowing amendment, the amendment merely clarifies the claim.

Claim 21 has been amended to delete reference to the label transfer pad. This is not a narrowing amendment, the amendment is made merely to clarify the claim.

Claim 22 has been amended to clarify that the end of the sample collector recited in the claim is the end that is opposite of the end of the sample collector that is in capillary communicating contact with the capture zone through the transit zone when the device is assembled. Support for the amendment can be found in the specification at page 25, lines 1-10 and Figures 1-3. This is not a narrowing amendment, the amendment merely clarifies the claim.

Claims 23 and 26 have been amended to clarify that the end of the sample collector recited in the claim is the end that is collector that is in capillary communicating contact with the capture zone through the transit zone when the device is assembled. Support for the amendment can be found in the specification at, *inter alia*, page 24, lines 11-21; page 12, lines 16-21; page 25, line 20 through page 26, line 10, and Figures 1-3. This is not a narrowing amendment, the amendment merely clarifies the claim.

Claim 31 has been amended to clarify that the end of the chromatography region recited in the claim is the end that makes contact with the sampler member when the device is assembled. Support for the amendment can be found in the specification at,

*inter alia*, page 13, line 22 through page 14, line 9 and Figure 5. This is not a narrowing amendment, the amendment merely clarifies the claim.

**Rejection of Claims 1-33 Under 35 U.S.C. §112, first paragraph**

Claims 1-33 stand rejected under 35 U.S.C. §112, first paragraph as allegedly lacking enablement. Applicants respectfully traverse the rejection.

The Office Action asserts that a housing holding the various members of the device is critical or essential to the practice of the invention and should be included in the claims. Applicants have amended claim 1 to recite a housing. The specification teaches that a housing can comprise either or both the sampler and detection components of the claimed device. See Specification, page 17, last paragraph. Applicants respectfully request withdrawal of the rejection.

**Rejection of Claims 1-33 Under 35 U.S.C. §112, second paragraph**

Claims 1-33 stand rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite. Applicants respectfully traverse the rejection.

**Claim 1**

The Office Action asserts that claim 1 is indefinite because it is unclear where the chromatography region is located with respect to the sampler member and the detection member. Claim 1 recites that the device comprises a chromatography region comprising a chromatography medium with a transit zone and a capture zone. Claim 1 furthermore recites that sample collector, which is associated with the sampler member, is in capillary communicating contact with the capture zone through the transit zone when the device is assembled into one part. As such the location of the chromatography region is clear.

The Office Action furthermore asserts that it is unclear where the sample collector is located with respect to the sampler member and the detection member. Claim 1 has been amended to recite that the sample collector is associated with the sampler member.

The Office Action additionally asserts that the phrase "upon separation of the device" is indefinite because it is unclear what the device is being separated from. However, the full phrase reads "upon separation of the device into the sampler member and the detection member." One of skill in the art, given the specification would understand that the phrase means that the device is separated into the sampler member and the detection member.

Therefore, claim 1 is definite.

#### **Claim 6**

The Office Action asserts that claim 6 is confusing. Claim 6 has been amended to address the Office's concerns. Therefore, claim 6 is definite.

#### **Claims 10 and 29**

The Office Action asserts that claims 10 and 29 are indefinite because it is unclear where the breakable container is located with respect to the device of claim 1. The Office Action asserts that it is unclear how the breakable container, the sampler and the detection member are being held together.

Claim 10 is dependent upon claim 7, which is, in turn, dependant upon claim 1. Claim 7 recites that the reagent delivery system delivers liquid reagent to the sample collector so that the liquid reagent flows through the sample collector. The breakable reagent container of claim 10 is part of the reagent delivery system. Therefore, the

reagent delivery system, comprising the breakable container, is positioned to deliver liquid reagent to the sample collector. As such, claim 10 is definite.

Claim 29 is dependant upon claim 28, which is dependant upon claim 7, which is dependant upon claim 1. Claim 7 recites that the reagent delivery system delivers liquid reagent to the sample collector so that the liquid reagent flows through the sample collector. Claim 28 recites that the reagent delivery system comprises an absorbent reagent pad. Claim 29 recites that the reagent delivery system further comprises at least one breakable reagent container and the absorbent reagent pad is positioned between at least one breakable reagent container and the sample collector. Claim 29, therefore, is definite because it specifies that the breakable containing is comprised within the reagent delivery system, which delivers liquid reagent to the sample collector so that the liquid reagent flows through the sample collector. As such Claim 29 is definite.

#### **Claims 11, 25, 26, 31, and 32**

The Office Action asserts that claims 11, 25, 26, 31, and 32 are confusing because they recite “a port”, which implies an opening in a housing. While applicants do not concede that a housing is necessary in order to have “a port”, a housing has been added to claim 1. As such, claims 11, 25, 26, 31, and 32 are definite.

#### **Claims 10, 15, 22, 23, 26, and 31**

The Office Action asserts that claims 10, 15, 22, 23, 26, and 31 are indefinite because it is unclear how the “proximal” and “distal” ends of the various parts are defined. The claims have been amended to remove reference to proximal and distal ends of the various parts. Therefore, claims 10, 15, 22, 23, 26, and 31 are definite.

#### **Claims 12 and 13**

The Office Action asserts that claims 12 and 13 are vague and indefinite because it is unclear where the sharp is located with respect to the various parts of the device. Claim 12 has been amended to recite that the sampler member comprises the sharp. Claims 12 and 13 are therefore definite.

#### **Claim 21**

The Office Action asserts that claim 21 is indefinite because the recitation of "label transfer pad" lacks antecedent support. Claim 21 has been amended to remove reference to the label transfer pad. Therefore, claim 21 is definite.

#### **Claim 33**

The Office Action asserts that claim 33 is confusing because it is unclear how an "air gap" is defined in a device without a housing. While applicants do not concede that a housing is necessary in order to have an air gap, "a housing has been added to claim 1. As such, claim 33 is definite.

Applicants respectfully request withdrawal of the rejection.

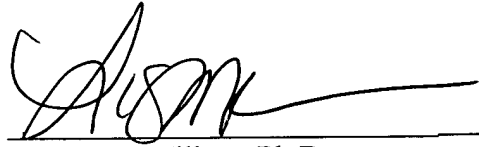
#### **Rejection of Claims 1-33 Under the Judicially Created Doctrine of Obviousness-Type Double Patenting**

Claims 1-33 stand rejected under the judicially created doctrine of obviousness-type double patenting. The Office Action alleges that claims 1-33 are unpatentable over claims 1-43 of U.S. Pat. No. 6,235,539. Applicants will submit a terminal disclaimer upon indication of allowability of the instant claims.

Respectfully submitted,  
**McDonnell Boehnen Hulbert & Berghoff**

Dated: 9/22/03

By:

A handwritten signature in black ink, appearing to read 'Lisa M. W. Hillman', written over a horizontal line.

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